NK

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,471	08/27/2001	William J. Rissmann	032580.0018.UTL	5252

22440 7590 10/08/2003

GOTTLIEB RACKMAN & REISMAN PC
270 MADISON AVENUE
8TH FLOOR
NEW YORK, NY 100160601

EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 10/08/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/940,471	Applicant(s) RISSMANN ET AL.	
	Examiner Kristen L Droesch	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-190* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-190* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 160-190 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 160 recites the limitation "the method" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 10-11, 17-19, 22-25, 32-34, 41-42, 48-50, 53-56, 64-65, 72-73, 79-81, 84-86, 88-89, 96-98, 105-106, 112-114, 117-120, 127-131, 138-139, 145-147, 150-153, 160-162, 169-170, 176-178, and 181-184, are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (5,827,326).

Regarding claims 1, 32, 63, and 160, Kroll et al. shows a power supply or voltage output system comprising a capacitor subsystem or energy storage system (332) and a battery subsystem or energy source system (370, 373; 301, 393, 397) electrically coupled to the capacitor (Figs. 23-24).

With respect to claims 2-3, 17, 33-34, 48, 64-65, 79, 97-98, 112, 130-131, 145, 161-162, and 176, Kroll et al. shows at three or more battery cells (370, 373; 301, 393, 397).

Regarding claims 10-11, 41-42, 72-73, 105-106, 138-139, and 169-170, Kroll et al. shows it is known to apply defibrillation energy at approximately 40 Joules (39.4 J) which falls within the range of approximately 40 to approximately 210 Joules, and approximately 40 to approximately 60 Joules (Col. 19, lines 25-30)

With respect to claims 18, 49, 80, 113, 146, and 177, Kroll et al. shows the at least one battery cell comprises a LiSVO battery cell (Col. 25, lines 9-12)

Regarding claims 19, 50, 81, 114, 147, and 178, Kroll et al. shows the capacitor subsystem has an effective capacitance of approximately 50μF to 200 μF (Col. 8, lines 35-37).

With respect to claims 22-23, 53-54, 84-85, 117-118, 150-151, and 181-182, Kroll et al. shows the cardioverter defibrillator is less than approximately 100 cc and less than approximately 50 cc in volume (Col. 8, lines 48-60).

Regarding claims 24-25, 55-56, 88-89, 119-120, 152-153, and 183-184, Kroll et al. shows the peak voltage is approximately 700 V to approximately 3150 V, and approximately 700 V to approximately 1050 V (Col. 11, lines 8-14).

With respect to claim 86, Kroll et al. shows the stimulation energy is cardioversion/ defibrillation energy.

Regarding claim 96, Kroll et al shows the housing has an electrically conductive surface and a lead assembly (16) that does not directly contact the heart or reside in the intrathoracic blood vessels (Col. 11, lines 64-66; Col. 12, lines 60-64).

With respect to claims 127-129, Kroll et al. shows the steps of generating cardioversion/defibrillation energy from an energy source system, storing the cardioversion/defibrillation energy in an energy storage system and delivering the cardioversion/defibrillation energy to the heart.

6. Claims 1, 5-11, 17, 19-21, 24-25, 32, 36-42, 48, 50-52, 55-56, 63, 67-73, 79, 81-83, 88-89, 127-129, 133-139, 145, 147-149, 152-153, 160, 164-170, 176, 178-180, and 183-184 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams (5,385,575).

Regarding claims 1, 32, 63, and 160, Adams shows a power supply or voltage output system comprising a capacitor subsystem or energy storage system (15a-b, 16a-b, 17a-b, 18a-b) and a battery subsystem or energy source system (11) electrically coupled to the capacitor (Fig. 3).

With respect to claims 5-9, 36-40, 67-71, 133-137, and 164-168, Adams shows six or more capacitors (15a-b, 16a-b, 17a-b, 18a-b) (Fig. 3).

Regarding claims 10-11, 41-42, 72-73, 138-139, and 169-170, Adams shows it is known to apply defibrillation energy at approximately 31-44 Joules which falls within the range of approximately 40 to approximately 210 Joules, and approximately 40 to approximately 60 Joules (Col. 2, lines 22-24)

With respect to claims 17, 48, 79, 145, and 176, Adams shows at least one battery cell (11) (Fig. 3).

Regarding claims 19-21, 50-52, 81-83, 147-149, and 178-180, Adams shows the capacitor subsystem has an effective capacitance of approximately 50μF to 200 μF, approximately 70μF, and approximately 100μF (Col. 6, lines 27-59).

With respect to claims 24-25, 55-56, 88-89, 152-153, and 183-184,Adams shows the peak voltage is approximately 700 V to approximately 3150 V, and approximately 700 V to approximately 1050 V (Col. 7, lines 52-54).

Regarding claim 86, Adams shows the stimulation energy is cardioversion/defibrillation energy.

With respect to claims 127-129, Adams shows the steps of generating cardioversion/defibrillation energy from an energy source system, storing the cardioversion/defibrillation energy in an energy storage system and delivering the cardioversion/defibrillation energy to the heart.

7. Claims 63, and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Stein (4,406,286).

Regarding claims 63 and 87, Stein shows a power supply or voltage output system comprising a capacitor subsystem (17) and a battery subsystem electrically coupled to the capacitor subsystem (Col. 4, lines 41-43) and the stimulation pulses comprise pacing pulses.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-4, 33-34, 64-66, 130-132, and 161-163 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,385,575). Adams discloses the claimed invention except for the battery subsystem or energy source comprising two, three, or four or more battery cells. It

would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the three battery cells as taught by Adams with two, three, or four or more battery cells, since applicant has not disclosed that this particular number of battery cells provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any number of battery cells such as the single battery cell taught by Adams for supplying power.

10. Claims 4, 34, 66, 99, 132, and 163 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (5,827,326). Kroll et al. discloses the claimed invention except for the battery subsystem or energy source system comprising four or more battery cells. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the three battery cells as taught by Kroll et al. with four or more battery cells, since applicant has not disclosed that this particular number of battery cells provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any number of battery cells such as the three battery cells taught by Kroll et al. for supplying power.

11. Claims 5-9, 36-40, 67-71, 100-104, 133-137, and 164-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (5,827,326). Kroll et al. discloses the claimed invention except for the capacitor subsystem or energy storage system comprising two, three, four, five, or six or more capacitors. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the capacitor as taught by Kroll et al. with two, three, four, five, or six or more capacitors, since applicant has not disclosed that this particular number of capacitors provides any criticality and /or unexpected results and it

appears that the invention would perform equally well with any number of capacitors such as the capacitor taught by Kroll et al. for storing power.

12. Claims 12-16, 43-47, 74-78, 140-144, and 171-175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,385,575). Adams discloses the claimed invention except for the defibrillation energy being approximately 60 to approximately 85 Joules, approximately 85 to approximately 115 Joules, approximately 115 to approximately 140 Joules, approximately 140 to approximately 160 Joules, and approximately 160 to approximately 210 Joules. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the defibrillation energy as taught by Adams with defibrillation energy being approximately 40 to approximately 210 Joules, approximately 40 to approximately 60 Joules, approximately 60 to approximately 85 Joules, approximately 85 to approximately 115 Joules, approximately 115 to approximately 140 Joules, approximately 140 to approximately 160 Joules, and approximately 160 to approximately 210 Joules, since applicant has not disclosed that these particular defibrillation energies provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any defibrillation energy such as 30 Joules taught by Adams for defibrillating the heart.

13. Claims 12-16, 43-47, 74-78, 107-11, 140-144, and 171-175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (5,827,326). Kroll et al. discloses the claimed invention except for the defibrillation energy being approximately 60 to approximately 85 Joules, approximately 85 to approximately 115 Joules, approximately 115 to approximately 140 Joules, approximately 140 to approximately 160 Joules, and approximately 160 to approximately 210 Joules. It would have been an obvious design choice to one with ordinary skill in the art at

the time the invention was made to modify the defibrillation energy as taught by Kroll et al. with defibrillation energy being approximately 40 to approximately 210 Joules, approximately 40 to approximately 60 Joules, approximately 60 to approximately 85 Joules, approximately 85 to approximately 115 Joules, approximately 115 to approximately 140 Joules, approximately 140 to approximately 160 Joules, and approximately 160 to approximately 210 Joules, since applicant has not disclosed that these particular defibrillation energies provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any defibrillation energy such as 30 Joules taught by Kroll et al. for defibrillating the heart.

14. Claims 20-21, 51-52, 82-83, 115-116, 148-149, and 179-180 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (5,827,326). Kroll et al. discloses the claimed invention except for the effective capacitance being specifically approximately 70μF, and approximately 100μF. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the effective capacitance of the capacitors as taught by Kroll with effective capacitance being specifically approximately 70μF, and approximately 100μF, since applicant has not disclosed that these particular effective capacitance values provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any effective capacitance such as 120μF, and 95μF taught by Kroll et al. for storing defibrillation energy.

15. Claims 26-31, 57-62, 90-95, 154-159, and 185-190 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,385,575). Adams discloses the claimed invention except for the peak voltage being approximately 1050 V to approximately 1400 V, approximately 1400 V to approximately 1750 V, approximately 1750 V to approximately 2100 V, approximately 2100

V to approximately 2450 V, approximately 2450 V to approximately 2800 V, and approximately 12800 V to approximately 3150 V. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the peak voltage as taught by Adams with peak voltages being approximately 1050 V to approximately 1400 V, approximately 1400 V to approximately 1750 V, approximately 1750 V to approximately 2100 V, approximately 2100 V to approximately 2450 V, approximately 2450 V to approximately 2800 V, and approximately 12800 V to approximately 3150 V, since applicant has not disclosed that these particular peak voltages provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any peak voltage such as 800 V taught by Adams for defibrillating the heart.

16. Claims 26-31, 57-62, 90-95, 121-126, 154-159, and 185-190 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (5,827,326). Kroll et al. discloses the claimed invention except for the peak voltage being approximately 1050 V to approximately 1400 V, approximately 1400 V to approximately 1750 V, approximately 1750 V to approximately 2100 V, approximately 2100 V to approximately 2450 V, approximately 2450 V to approximately 2800 V, and approximately 12800 V to approximately 3150 V. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the peak voltage as taught by Kroll et al. with peak voltages being approximately 1050 V to approximately 1400 V, approximately 1400 V to approximately 1750 V, approximately 1750 V to approximately 2100 V, approximately 2100 V to approximately 2450 V, approximately 2450 V to approximately 2800 V, and approximately 12800 V to approximately 3150 V, since applicant has not disclosed that these particular peak voltages provide any criticality and /or

unexpected results and it appears that the invention would perform equally well with any peak voltage such as 750 V taught by Kroll et al. for defibrillating the heart.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Swerdflow et al. (6,091,989) shows a defibrillator with a capacitor system having a range of values from 10μF to 250μF that stores up to 40J of energy and may be charged to 1000V for delivering defibrillation shocks.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

kld

Angela D Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700